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DreamTeamGroup

DTG Street Beat Blog

CATEGORY ARCHIVES: GALENA BIOPHARMA INC. GALE

Galena Biopharma (GALE) a Favored Buy, Says Seeking Alpha Contributor

This entry was posted in [Galena Biopharma Inc. GALE](#) on November 27, 2013 by [MissionIR](#).

Galena Biopharma was recently the topic of a Seeking Alpha article by contributor “Stock Whisper.” The article discusses the trading activity of Galena stock, recently analyst coverage, as well as current and potential sales figures.

To read the article in its entirety visit <http://seekingalpha.com/article/1865671>

Shares of Galena have soared nearly 60 percent since November 11 when the company issued its phase I trial results of its Folate Binding Protein (FBP) vaccine for endometrial and ovarian cancer. The rally accrued additional investor interest and was further fueled by analyst action.

Oppenheimer Monday initiated an Outperform rating on Galena’s stock and set a 12-18-month price target of \$6.

“The coverage by Oppenheimer came as positive news, as it further strengthens the positive sentiment surrounding the company, which was translated into the share prices yesterday. The pipeline candidates of Galena are indeed promising, having expected blockbuster potential,” the article states.

Referencing Galena’s marketing of Abstral®, for which the company reported \$1.2 million in sales before the official product launch, Stock Whisper writes, “Hence, it is right to say that Abstral in the coming quarters may prove to be a major value creator for the company and help pave the way towards a profitable company.”

The article also discusses NeuVax, the company’s potential blockbuster drug for breast cancer treatment and its opportunity in the healthcare market.



In conclusion, the article dubs Galena “a fair investment, with major long term potential. The current price is a profitable entry point for long term investors as the share prices are bound to take off and will bring in huge gains.”

For more information, visit www.galenabiopharma.com

Let us hear your thoughts below:

Oppenheimer Initiates Outperform Rating on Galena Biopharma, Inc. (GALE), Sets \$6 Price Target

This entry was posted in [Galena Biopharma Inc. GALE](#) on November 26, 2013 by [MissionIR](#).

Analysts at Oppenheimer initiated coverage of Galena Biopharma, placing an Outperform rating on the stock with a 12-18-month price target of \$6. The firm centered its valuation on Galena’s NeuVax drug candidate and recently commercialized Abstral.

Galena is developing and commercializing a portfolio of oncology treatments to address unmet medical needs. Among other candidates is NeuVax, for the treatment of breast cancer – the company expects to complete the NeuVax phase 3 enrollment early next year. Abstral® is the company’s FDA-approved therapy designed to improve the quality of life for cancer patients suffering from breakthrough cancer pain but that have developed a tolerance to opioid (narcotic) pain management.

Oppenheimer touched on the following key items, as quoted:

- “In our view, the Phase I/II study of NeuVax met its goal of confirming NeuVax’s safety, identifying patients with the best response, and providing sufficient information to commence a pivotal (PRESENT) study. We are optimistic about the PRESENT study outcome.
- “Some investors expressed concern due to the inverse correlation of NeuVax response and HER2 expression level. While a correlation would be expected for an antibody treatment, we believe that vaccines don’t have to correlate to antigen expression. In some cases, high antigen expression may lead to immune tolerance.
- “Commercially, we believe that NeuVax has no direct competition. Despite several recent new drugs to treat HER2 positive breast cancer, these drugs target only the high expressors. As such, the low HER2 expression patients have no targeted therapy options.
- “In addition to NeuVax, Galena recently commenced actively marketing Abstral for breakthrough cancer pain. As a sublingual fentanyl tablet, Abstral offers an attractive therapeutic option for some patients. We currently view Abstral as an upside to our valuation.
- “The key milestones for Galena include ongoing Abstral scripts and quarterly results, an update on NeuVax at the SABCS conference on December 10-14th, and commencement of the FBP Phase I/II study around year-end.”

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Galena Biopharma, Inc. (GALE) Scheduled to Present at the 25th Annual Piper Jaffray Healthcare Conference

This entry was posted in [Galena Biopharma Inc. GALE](#) on November 26, 2013 by [MissionIR](#).

Galena Biopharma, a biopharmaceutical company focused on targeted treatments for cancer, today announced that President and CEO Mark J. Ahn, Ph.D., will be presenting a corporate update at the 25th Annual Piper Jaffray Healthcare Conference. The presentation will take place on Tuesday, December 3, 2013 at 8:10 a.m. ET at The New York Palace Hotel in New York, NY.

The presentation will be available on the Investors section of the company's website at www.galenabiopharma.com

Let us hear your thoughts below:

Galena Biopharma, Inc. (GALE) Receives Bullish Review at Seeking Alpha

This entry was posted in [Galena Biopharma Inc. GALE](#) on November 22, 2013 by [MissionIR](#).

Galena Biopharma has been highlighted in a Seeking Alpha article for its performance in developing breakthrough oncology treatments for various forms of cancer.

Contributing writer Kingmaker discusses the company's Folate Binding Protein (FBP) and financial position, as well as provides a technical chart, before concluding that, "Galena Biopharma appears to be one company that deserves at least a small allocation of capital. By building a diversified portfolio of breakthrough treatments and products, corporate management appears to be serious about building a global biotechnology company that can grow significantly during the years to come."

To read the article in its entirety visit <http://seekingalpha.com/article/1857581>

Galena is currently conducting a phase 1 FBP trial to prevent endometrial and ovarian cancer recurrences in patients who have already undergone therapy and are disease-free. So far, the company has determined optimal dose and found FBP's toxicity to be minimal in addition to favorable follow-up.

"Investors should also note the results from the company's 6-month follow-up. The vaccine group only demonstrated 2 recurrences, a total



For the third quarter of 2013, Galena reported an improvement of approximately \$56.8 million in cash, cash equivalents and short-term investments, as compared to previous quarters. The article recaps the company's financial performance and notes upcoming potential.

"As investors soak in the promising early results from the FBP Phase 1 trial, they should also be aware that Galena continues to push forward with NeuVax (used in the treatment of breast cancer). The company expects to complete the NeuVax Phase 3 enrollment early next year. Galena also expects to announce interim results based upon 70 events by the summer of 2014 at the very latest. If positive, these interim results will likely send the shares to new 52-week highs. In fact, biotech companies typically see significant share price runs over the course of a Phase 3 trial, up until the results are announced. If investors have a reason to believe the results will be positive, Galena could end up being the biotech stock of 2014," writes Kingmaker.

For more information, visit www.galenabiopharma.com

Let us hear your thoughts below:

Galena Biopharma, Inc. (GALE) Anticipates Continued Growth on Strong Clinical Pipeline, Abstral Performance

This entry was posted in [Galena Biopharma Inc. GALE](#) on [November 19, 2013](#) by [MissionIR](#).

Galena Biopharma is a developer of targeted oncology treatments designed to address major unmet medical needs to advance cancer care. As part of its overarching goals, Galena is seeking commercialization partners for its current clinical programs.

The company's clinical development pipeline is headed by NeuVax™, which has been granted by the FDA a Special Protocol Assessment (SPA) for a phase 3 clinical trial testing the product's efficacy to prevent breast cancer recurrence. NeuVax is currently undergoing this phase 3 testing in combination with Herceptin®; phase 2 for breast cancer; and phase 1 for prostate cancer.

Galena is also developing Folate Binding Protein-E39 (FBP), a targeted vaccine aimed at preventing the recurrence of ovarian, endometrial and breast cancers. FBP is in phase 1 studies for this indication.

The company in October officially launched Abstral®, its sublingual (under the tongue) rapid-acting formulation of fentanyl for the management of breakthrough cancer pain in patients who are tolerant to background opioid pain-relief therapy.

When the company earlier this month reported third-quarter revenues of \$1.2 million, the results reflected significant contribution of Abstral sales ahead of the product's official launch and promotional efforts slated for the fourth quarter.

Abstral has achieved considerable success as the leading rapid acting fentanyl product in Europe, where it achieved full-year sales of \$54 million by ProStrakan/Kyowa Hakko Kirin in 2012. By the second half of 2012, the average volume market share of Abstral in the major European markets reached 29%. Abstral is marketed in Canada by Paladin Labs, and has been filed for regulatory approval in Japan by Ky-



initial commercial success with Abstral, Galena said it expects to see continued growth in the fourth quarter of 2013 and fiscal 2014.

For more information, visit www.galenabiopharma.com

Let us hear your thoughts below:

Galena Biopharma, Inc. (GALE) Receives Favorable Analyst Coverage Following Q3 Results, Product Reviews

This entry was posted in [Galena Biopharma Inc. GALE](#) on November 12, 2013 by [MissionIR](#).

Biotech small-cap Galena Biopharma has garnered significant analyst coverage in lieu of recent product developments and financial results. Galena currently has five programs in various stages of clinical development, including NeuVax, in phase III for breast cancer, and Folate Binding Protein vaccine (FBP) in phase I/II for gynecological cancers. In addition, Abstral® is the company's FDA-approved treatment option for breakthrough cancer pain. Galena acquired Abstral in March 2013, and officially launched the drug in the U.S. in October.

Analyst Coverage

Needham & Company maintained a Buy rating on Galena stock with a price target set at \$3.50, basing its valuation primarily on the company's NeuVax candidate, also noting Abstral's upside potential. Needham analyst Chad Messer, Ph.D., says:

"We maintain our Buy rating and \$3.50 price target on Galena. Our target is based on a \$324 million enterprise value for NeuVax. ... Abstral could perform better than expectations. NeuVax could succeed in its pivotal clinical trial and exceed sales expectations in breast cancer patients. Galena could partner NeuVax. Galena could advance earlier stage programs including its phase II trial of NeuVax in combination with Herceptin."

Zacks reiterated its valuation on GALE with a 12-month PT of \$4.50 with an Outperform rating, labeling NeuVax "blockbuster potential" if the product is brought to market. In his note, Grant Zeng, CFA, says:

"It's a surprise to us that GALE reported Abstral sales ahead of its official launch and we are pleased with the initial commercial success to date with Abstral which is very encouraging. With its sales force and commercial organization fully deployed, GALE continues to make significant strides with physicians, payors and patients and expect continuing strength with the launch. As a result, we expect to see continued Abstral sales growth in the fourth quarter of 2013 and fiscal 2014."

Noble analyst Rahul Jasuja, Ph.D., in a note reaffirmed his Buy rating and \$4 price target on the stock, saying:

"The development of NeuVax for breast cancer has a long history that has helped optimize the cancer vaccine for a specific clinical setting in breast cancer, giving it a greater chance of success. The clinical development, led by Dr. George Peoples and others, over more than a decade



Additional Analyst Coverage for Galena

- Cantor Fitzgerald's Maria Goldstein issued a Buy rating and a price target of \$4.
- MLV & Co. maintained a Buy rating and a \$6 price target on the stock, issuing two analyst notes to separately discuss the Galena's Q3 results and FBP.
- Roth Capital issued two analyst notes to separately highlight the company's Q3 results and FBP – the firm reiterated a Buy rating and a price target of \$7 on the stock.
- JMP Securities maintained a Market Outperform rating and a \$5 price target.

For more information, visit www.galenabiopharma.com

Let us hear your thoughts below:

Galena Biopharma, Inc.'s (GALE) Posts Q3, Nine-Month Results – Abstral® Debut in U.S. Generates Q3 Revenues of \$1.2M

This entry was posted in [Galena Biopharma Inc. GALE](#) on [November 7, 2013](#) by [MissionIR](#).

Galena Biopharma opened its books Wednesday in after-hours trade, with the biopharm company posting third-quarter and nine-month financial results for the periods ended September 30, 2013, and issuing a business update.

Third-quarter revenues of \$1.2 million reflect the first quarter of Abstral® (fentanyl) sublingual tablet sales, prior to the company's official launch and commencement of promotional efforts in the fourth quarter. Net loss for the quarter was \$0.11 per basic and diluted share, versus a net loss of \$0.09 per basic and diluted share as reported for the comparable quarter of 2012.

Abstral® is the company's FDA-approved treatment option for breakthrough cancer pain. Galena in March 2013 acquired Abstral®, and in May 2013 completed a debt financing of \$15 million to fund the purchase and launch of the product, of which \$10 million was drawn immediately and \$5 million remains available. Abstral® was officially launched in the U.S. in October.

"Our commercial success to date with Abstral® has been very encouraging and we are excited to report initial revenues ahead of schedule. With our sales force and commercial organization fully deployed, we continue to make significant strides with physicians, payors and patients—and expect continuing strength with the launch," Mark J. Ahn, Ph.D., president and CEO of Galena stated in the news release. "We are also making steady progress in advancing our NeuVax™ and FBP cancer immunotherapy pipeline."

For the nine-month period, Galena reported a net loss of \$0.34 per basic and diluted share, versus a net loss (including both continued operations and discontinued operations) of \$ \$0.52 per basic and diluted share for the first nine months of 2012.



The company also provide a brief look at its third-quarter and recent achievements, including the commercial launch of Abstral®. Galena also noted:

- Appointment of Dr. Brian Hamilton, M.D., Ph.D. to serve as executive vice president and chief medical officer.
- Phase 3 PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax™ Treatment) trial, under an SPA, enrolling at approximately 130 sites globally.
- Phase 2b NeuVax plus Herceptin® (trastuzumab; Genentech/Roche) 300 patient randomized, combination trial is enrolling at nine sites in the U.S.
- Results from the phase 1 portion of the Folate Binding Protein (FBP) trial will be presented at the Society for Immunotherapy of Cancer (SITC) conference taking place November 7-10, 2013. Expanded NeuVax™ Intellectual Property With European Allowance.
- NeuVax Oral presentation at the American College of Surgeons Clinical Congress.
- Secured \$40 million in financing to significantly strengthen its balance sheet.

For more information visit www.galenabiopharma.com

Let us hear your thoughts below:

Galena Biopharma, Inc. (GALE) Wraps Up a Landmark Month

This entry was posted in [Galena Biopharma Inc. GALE](#), [Stock to Watch](#) on November 5, 2013 by [MissionIR](#).

October was a full month for oncology-focused biopharmaceutical company Galena Biopharma, Inc.

The company began the month with a milestone announcement of the official U.S. product launch of its Abstral (fentanyl) Sublingual Tablets for the management of breakthrough cancer pain. The product was acquired by Galena in March of 2013 and has become the company's first commercial product, offering relief from breakthrough pain to cancer patients who have become opioid-tolerant. Abstral can now be prescribed by healthcare professionals and is available at retail pharmacies nationwide.

Galena also traveled the conference circuit last month, presenting at the 12th annual BIO Investor Forum, which took place Oct. 9 in San Francisco, Calif., and also making a presentation at the American College of Surgeons Clinical Congress 2013, which took place Oct. 6-10 in Washington, D.C.

The company's presentation at the American College of Surgeons Clinical Congress, titled "Predicting Clinical Benefit After Completion of Treatment with the Adjuvant Breast Cancer Vaccine NeuVax (nelipepimut-S or E75)," gave an analysis of biomarker data and clinical outcomes from the NeuVax Phase 2 trial.

A cancer immunotherapy that harnesses the immune system's power to seek out and destroy HER2-presenting cancer cells, NeuVax is the most immunogenic peptide of the HER2 protein, which is injected into the body to allow the immune system to develop a strong HER2-directed T-cell response, creating immune memory and priming the immune system against tumor cells. This active immunotherapy is able to



In the company's presentation, various variables were analyzed, including HER2 levels, the effect of boosters, induction and amplification of the NeuVax T-cell response. The data shows that induction, rather than amplification, of an anti-HER2 immune response provides optimal clinical benefit and may partially explain why NeuVax works in HER2 IHC 1+/2+ patients with low to intermediate HER2 antigen exposure. The data is consistent with previously published biomarker data that indicates a correlation between increasing NeuVax-specific T-cells after vaccination and reductions in breast cancer recurrence rates.

As Galena heads into November, the company continues efforts to advance its pipeline of products toward approval. For more information about the company, including its current clinical development efforts, visit www.galenabiopharma.com.

Let us hear your thoughts below:

Galena Biopharma, Inc. (GALE) CEO Dr. Mark Ahn is Well-Versed in Biopharm, Corporate Management

This entry was posted in [Galena Biopharma Inc. GALE](#) on [October 29, 2013](#) by [MissionIR](#).

Galena Biopharma is a biopharmaceutical company focused on developing and commercializing treatments to address major unmet medical needs in the field of oncology. As GALE works to expand its drug candidate portfolio, the company's stated mission is to accelerate value for both patients and company shareholders, a goal that requires support and guidance from an experienced and aggressive management team.


Leading the company's corporate initiatives is Mark J. Ahn, Ph.D., who has more than 20 years of experience in the biopharmaceutical industry. Dr. Ahn has served as GALE's president and CEO since March 2011, and has also served as a director of the company since 2007.

Prior to joining GALE, Dr. Ahn was principal at Pukana Partners, Ltd., which provides strategic consulting to life science companies; and associate professor of Global Management at Atkinson Graduate School of Management, Willamette University. He also previously served as professor and chair of Science & Technology Management for Victoria University at Wellington, New Zealand.

Dr. Ahn was also founder and was previously the president and CEO of Hana Biosciences following his employment as vice president of Hematology and corporate officer at Genentech, Inc. In addition, he has held positions of increasing responsibility at Amgen (AMGN) and Bristol-Myers Squibb (BMY).

Dr. Ahn has authored more than 50 peer reviewed journal articles and books, and serves on public and venture capital-backed board of directors for Access Pharmaceuticals, Mesynthes, and ScribesSTAT. He received a BA and an MBA from Chaminade University, as well as an MA from Victoria University. Furthermore, Dr. Ahn was a graduate fellow in economics at Essex University, and obtained a Ph.D. from the University of South Australia. Dr. Ahn is a Henry Crown Fellow at the Aspen Institute.

For more information visit www.galenabiopharma.com

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Biotech Bonanza

This entry was posted in [Galena Biopharma Inc. GALE](#) on [October 21, 2013](#) by [MissionIR](#).

Biotech companies often return incredible investment rewards. Ten-fold, twenty-fold, and even a hundred-fold return can occur over time after a company announces the approval of a breakthrough drug and moves solidly into commercialization.

Medivation (MDVN) tops the list of top biotech blockbusters over the last decade with gains of more than 11,000%. To put that in perspective, an investment of \$10,000 in this biotech back in 2003 would now be worth over \$1 million. Questcor Pharmaceuticals (QCOR) shares zoomed up more than 5,000% in the past decade and Illumina (ILMN) soared more than 3,900% during the past 10 years.

It's probably no surprise that the upward ride for these companies wasn't smooth and steady, proving that the best investing approach is to choose great companies and stick with them for the long term. The trouble is that picking the next big winner can be tricky.

There are, however, a few well tested criteria that help in the search for the next biotech bonanza. First, look for companies with drugs that treat rare and devastating diseases and that have products in stage II or III of testing. Second, look at companies that have received a recent FDA approval for one of their drugs. Third, look for a company with a pipeline of drugs and the capital resources to bring them to market. Finally, it's important to consider market size and patient demand in biotech drug development. Oncology was named the top the drug development field for 2013 and beyond by The Life Sciences Report/Sagient Research Watchlist.

Given these criteria, Galena Biopharma, Inc. (NASDAQ: GALE) is worthy of consideration. Galena Biopharma develops and commercializes innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care. The company just announced the official commercial product launch of Abstral® Sublingual Tablets in the United States. Abstral® is a sublingual fentanyl tablet used for the management of breakthrough pain in cancer patients.

GALE also has multiple cancer drugs in various stages of development. Based on a very successful Phase II trial, the (FDA) granted Galena's NeuVax™ a Special Protocol Assessment (SPA) for a Phase III clinical trial. NeuVax™ is a treatment for breast cancer patients to forestall or defeat cancer recurrence and it's showing excellent results. If approved by the FDA, NeuVax™ will be the first of its kind in an even wider scope than the widely used drug Herceptin. The Herceptin drug market alone is roughly \$7 billion and the market potential for NeuVax™ could be enormous. The drug is in Stages 1 through 3 clinical trials for other breast cancer treatments and for prostate cancer. GALE is also entering phase two trials with a targeted vaccine (Folate Binding Protein-E39) aimed at preventing the recurrence of ovarian, endometrial, and breast cancers.

To complement the rollout of their first commercial product Galena Biopharma recently completed a firm commitment underwriting led by Oppenheimer & Co. This offering delivered over \$37 million to Galena and they intend to use the proceeds for the commercialization of Abstral®, their ongoing Phase 3 NeuVax™ clinical trial, corporate expenses, plus their other clinical trials.

The next biotech bonanza just might be underway.

For more information, visit www.galenabiopharma.com

